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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,852	02/04/2004	Jeffrey W. Ruberti	42222-0006	9743

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EXAMINER	
EGWIM, KELECHI CHIDI	
ART UNIT	**PAPER NUMBER**
1713	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,852	RUBERTI ET AL.	
	Examiner	Art Unit	
	Dr. Kelechi C. Egwim	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *113-119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *113-119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Due to amendments and persuasive arguments by applicant, the previous rejections of record based on Ottoboni et al. have been overcome and are hereby withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 113 is rejected under 35 U.S.C. 102(b) as being anticipated by Hyon et al., Tanihara et al., Ku et al., Yao et al., Yamauchi et al. or Okamura, for reasons cited in the previous action.

4. Claims 114-119 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, 35 U.S.C. 103(a) as being unpatentable over Tanihara et al., Ku et al., Yao et al., or Okamura, for reasons cited in the previous action.

Response to Arguments

5. Applicant's arguments filed 08/18/2006 have been fully considered but they are not persuasive.

6. Regarding Hyon et al., Ku et al., Yao et al. and Okamura, applicant states that the "[f]reeze-thaw process does not permit preparation of an injectable formulation" and "[the] Hyon method can not yield an injectable hydrogel", but provides insufficient evidence to support these conclusionary statements. Simply saying that the hydrogels are not or would not be injectable is not sufficient evidence to prove so.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a hydrogel without the freeze-thaw treatment) are not actually recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Further, in col. 9, lines 58-67, Yao et al. teach that depending on the end use, the hydrogel can be repeatedly freeze-thawed to increase it's viscosity. Thus, after one cycle, the hydrogel would still be at least injectable. Yao et al only require one cycle to form the hydrogel.

7. Regarding Tanihara et al., regardless of the purpose of including the salts in the composition Tanihara (as gallants and/or therapeutic / modulus modifier), the claim only requires that they are present. Any addition benefits from their presence would be inherent

Further, the statement that "[the] Tanihara [hydro]gel is not injectable" is conclusionary and not supported by evidence ,either provided by or pointed to by applicant.

8. Regarding Yamauchi et al., applicant argues " Yamauchi explicitly states that the hydrogel is formed from covalently-bonded PVA through ionizing radiation". However applicant has failed to point out where specifically such language is to be "explicitly" found in Yamauchi et al. While Yamauchi et al. teach that the hydrogel has a there dimensional structure, there is nothing found by the examiner in the reference to require that its crosslinking be exclusively covalent as suggested by applicant.

Further, with a big enough injector, any gel/hydrogel can be injected.

9. Regarding the 102-/103 rejections, the examiner contends that generic disclosure of the claimed hydrogel continues to be present in the cited art reference, for reasons indicated above.

10. Regarding the "substantially free of chemical crosslinkers" language, the examiner reminds applicant that this is not the same as "free of chemicals crosslinkers". Applicant had failed to demonstrate that the crosslinking in the cited prior art is not "substantially free" of chemical crosslink as defined in and consistent with the present claims.

11. **THIS ACTION** IS **MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kelechi C. Egwim whose telephone number is (571) 272-1099. The examiner can normally be reached on M-T (7:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KELECHI C. EGWIM PH.D.
PRIMARY EXAMINER

KCE